REMARKS

Claims 1-10 and 27-40, 42-44 and 46-54 are pending in the application with entry of this amendment. Claims 1, 3, 4, 6, 7, 10, 27-30, 32, 37-40, 42-44, 46, 47 and 50 are currently amended. Various claims are amended for form to refer to an ablation electrode or ablating tissue rather than a coagulation electrode or coagulating tissue. The amendments do not present new matter.

For example, the subject application explains that "[e]lectromagnetic radio frequency ("RF") energy applied by the electrode heats, and eventually kills (i.e. 'ablates'), the tissue to form a lesion. During the ablation of soft tissue (i.e. tissue other than blood, bone and connective tissue), tissue coagulation occurs and it is the coagulation that kills the tissue. Thus, references to the ablation of soft tissue are necessarily references to soft tissue coagulation. 'Tissue coagulation' is the process of cross-linking proteins in tissue to cause the tissue to jell. In soft tissue, it is the fluid within the tissue cell membranes that jells to kill the cells, thereby killing the tissue."

The subject application also explains that with embodiments, in addition to forming lesions, surgical systems may also be used to "determine whether or not therapeutic lesions have been properly formed by, for example, supplying tissue stimulation energy on one side of a lesion. The tissue on the other side of the lesion may then be monitored to determine whether an excitation block (typically the result of a continuous transmural lesion) has been formed in the target tissue. Tissue stimulation energy may also be used to determine lesion depth, which in turn, allows the physician to determine whether or not a lesion is transmural."

Further, the subject application explains that "the present surgical systems may be used to test the effectiveness of a lesion as follows. After the lesion is formed, the physician may use the same surgical device that was used to form the lesion (e.g. the surgical probe, surgical probe and suction device, or clamp based electrophysiology device) to perform a lesion evaluation. As discussed in greater detail below, the stimulation electrodes that are provided on surgical devices may be used to stimulate tissue on one side of a lesion by pacing at a higher rate than normal (e.g. 120 beats/minute). The local activation, if any, on the other side of the lesion will indicate whether or not the excitation block is incomplete. The stimulation electrodes may also be used to sense tissue within an isolated tissue region around which a lesion has been formed. Local

activation within the isolated region from the heart's natural stimulation is indicative of a gap in the lesion. Additionally, the stimulation electrodes may be used to determine lesion depth."

Dependent claims 7, 37 and 38 are withdrawn from consideration. Allowance of these claims is respectfully requested upon allowance of a corresponding independent claim.

Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Clarification of Rejections

Applicant appreciates the Examiner clarifying that certain rejections are based on U.S. Patent No. 5,931,811 to Haissaguerrre ("Haissaguerre") rather than another patent to "Nelson." The following remarks address Haissaguerre.

II. Withdrawn Rejections

Applicant acknowledges that the following rejections in the Office Action mailed on June 12, 2008 have been withdrawn:

1. Rejection of claims 27-34, 36, 39, 40, 42-44 and 46 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,755,760 to Maguire *et al.* ("Maguire") in view of U.S. Patent No. 6,286,512 to Loeb *et al.* ("Loeb").
2. Rejection of claim 35 under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of Loeb and further in view of U.S. Patent No. 5,931,811 to Haissaguerrre ("Haissaguerre").

III. Erroneous Grammatical Interpretation of Cited Section of Loeb

It is alleged in page 3 of the Office Action that Loeb discloses an electrosurgical device having spaced mapping electrode rings 715, and that it is known to use these mapping electrode rings to "provide for electrically mapping the heart by receiving and transmitting electrical signals related to the operation of that organ to recording signal processing and display devices." Office Action (p. 3, citing Loeb, col. 15, 27-57). Based on this cited section, it is alleged that Loeb discloses that these mapping electrodes both transmit (send, deliver) electrical signals and, in addition, receive electrical signals. Office Action (p. 3, line 11-14).

The particular section of Loeb discussed above and relied upon in the Office Action is at col. 15, lines 53-57. The paragraph as it recited in Loeb is reproduced below for reference:

> Preferably, attached to the cannula distal end portion 773 are serially spaced mapping electrode rings 715 for monitoring parts of the body. Such mapping electrodes are known in the art and, for example, provide for electrically mapping the heart by receiving and transmitting electrical signals related to the operation of that organ to recording signal processing and display devices. Additionally or

> alternatively, the cannula distal end may be made of a radio-opaque material so that the position of the cannula within the heart chamber can be viewed under fluoroscopy, ultrasound or other imaging techniques. Loeb (col. 15, lines 53-57).

The same paragraph of Loeb is reproduced below with emphasis to point out how this section of Loeb is grammatically structured, properly interpreted, and how the Office Action allegation is not supported by this interpretation.

> Preferably, attached to the cannula distal end portion 773 are serially spaced mapping electrode rings 715 for monitoring parts of the body. Such mapping electrodes are known in the art and, for example, provide for electrically mapping the heart by receiving and **transmitting** electrical signals related to the operation of that organ **to** recording signal processing and display devices. Additionally or alternatively, the cannula distal end may be made of a radio-opaque material so that the position of the cannula within the heart chamber can be viewed under fluoroscopy, ultrasound or other imaging techniques. Loeb (col. 15, lines 53-57) (emphasis added).

As is readily appreciated by interpreting the above paragraph correctly according to its actual grammatical structure, Loeb explains that mapping the heart involves:

1. receiving electrical signals related to the operation of the heart (as is well known in mapping applications), and then
2. transmitting those received electrical signals to recording signal processing and display devices.

Thus, Loeb describes a particular sequence of steps that are performed with known mapping electrode rings, *i.e.*, that signals are first received from the heart (as is well known in mapping applications), and then these signals are transmitted to signal processing and display devices.

This interpretation and sequence are also consistent with the fact that Loeb refers to "receiving" first, and then "transmitting" thereafter.

This interpretation and sequence are also consistent with the fact that Loeb explains that the signals that are received and then transmitted are "related to the operation of that organ." In other words, the electrical signals that are "related to the heart" are the electrical signals generated by the heart, *i.e.* the signals that are received from the heart, and then these received

signals are transmitted to signal processing and display devices (as is well known in mapping applications).

Accordingly, based on the correct grammatical interpretation of the cited paragraph, Loeb does not disclose that known mapping electrodes transmit signals, then receive signals, then transmit signals since such an interpretation would not make any sense because the cited sentence continues to state that something (*i.e.*, the received signals) are transmitted "**to**" recording signal processing and display devices. Thus, based on the Office Action allegation, there would be three steps: 1. transmitting stimulation energy; 2. receiving electrical signals related to the heart; and 3. transmitting those received signals to signal processing and display devices, but Loeb actually describes a specific sequence of two steps: 1. receiving electrical signals related to the heart; and 2. transmitting those received signals to signal processing and display devices, as is well known in mapping applications. The fact is that Loeb does not disclose two "transmitting" steps and instead only discloses a transmitting step that follows receiving electrical signals related to the heart utilizing mapping electrodes, is consistent with the fact that Loeb refers to transmitting in only one instance (after receiving) and the understanding of how mapping is actually performed.

For example, referring to Appendix 1, cardiac mapping is defined as "a method by which potentials **recorded directly from the surface of the heart** are **spatially depicted** as a function of time in an integrated manner." Cardiac Mapping – Second Edition (p. 15, col. 1, para. 2) (emphasis added). Thus, this reference explains that potentials that are already recorded (past tense) are then spatially depicted (or displayed). This definition is consistent with the correct interpretation of Loeb as explained above, *i.e.*, that the heart is mapped by first receiving electrical signals, and then those received signals are transmitted to a signal processing or display device.

As another example, Appendix 1 also explains that "cardiac mapping usually refers to **measuring** the electrical activity of the heart in 2 or 3 dimensions and **displaying that activity** on 2-dimensional representations." Cardiac Mapping – Second Edition (p. 41, col. 1, para. 2) (emphasis added).

Further, as discussed in the prior amendment, various other patents describe known mapping procedures in a manner that is consistent with Applicant's interpretation and remarks above. For example, a person of ordinary skill in the art would readily appreciate the differences

between a stimulation electrode as recited in Applicant's claims and known mapping electrodes since mapping electrodes are used before ablation of tissue (as explained in U.S. Patent Nos. 5,964,753 and 6,360,128). Therefore, it logically follows that such mapping electrodes are also used before a lesion is formed since a lesion is formed as a result of ablation. Accordingly, based on what is described by U.S. Patent Nos. 5,964,753 and 6,360,128, it is understood that a mapping electrode is not a stimulation electrode since mapping electrodes are used before formation of a lesion, and before use of "a stimulation element configured to emit energy to tissue for stimulating tissue and **evaluating formation of the lesion**..."" as recited in claims 1, 27 and 30. Even if a mapping electrode is used after formation of a lesion, the mapping electrode nevertheless operates as a sensor or antenna for receiving and **monitoring** the electrical signals of the heart as opposed to emitting stimulation energy for evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

Consistent with Applicant's interpretation and the understanding by a person of ordinary skill in the art is the fact that the Office Action has cited no reference that describes known mapping electrodes being capable of use, or used for, stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

IV. Claims 1-6, 9 and 10 Are Patentable Over Maguire and Loeb

Independent claim 1 and dependent claims 2-6, 9 and 10 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of Loeb. Applicant respectfully traverses the rejection.

It is conceded that Maguire fails to disclose mapping electrodes configured to emit energy to tissue for stimulation tissue and evaluating formation of the lesion. Office Action (p. 3, lines 3-4). Accordingly, it is Applicant's understanding that it is also conceded that Maguire fails to disclose the combination of "an ablation element configured to emit energy for ablating tissue and forming a lesion within tissue, the ablation element defining an ablation element configuration on the distal region of the relatively short tubular shaft" and "a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of

ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the ablation element configuration" as recited in claim 1.

Claim 1 recites:

1. a "stimulation" element, not a "mapping electrode" or simply an "electrode";

2. a stimulation element configured to emit energy to tissue as opposed to an electrode that simply receives or detects electrical signals;

3. a stimulation element configured to evaluate formation of the lesion (which results from tissue ablation by a coagulation element) by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

It is alleged in the Office Action that the coil electrodes 12 and/or 16 define "a coagulation element configuration," and that the electrode 20 and alternate components define "a stimulation configuration." Office Action (p. 2). However, this is not what is actually described by Maguire since Maguire explains that the electrode 20 is a cardiac mapping electrode. Maguire (col. 3, lines 51-52; col. 4, lines 47-48).

It is known that a cardiac mapping electrode serves as a sensor or antenna for detecting electrical activity of the heart. For example, col. 1, lines 38-50 of U.S. Patent No. 6,063,080 (cited in a prior Office Action) explains that cardiac mapping is used to identify a potential ablation site. This procedure involves inserting a catheter having multiple electrodes into the heart and **monitoring** the electrical signals of the heart in order to identify tissue causing an arrhythmia. In this manner, cardiac mapping electrodes "serve as **individual antennas for detecting** the electrical activity of the heart in the area corresponding to that electrode. As a further example, U.S. Patent Nos. 5,964,753 and 6,360,128 provide other similar descriptions of cardiac mapping procedures and electrodes and explain that cardiac mapping can be used before ablation to locate aberrant conductive pathways within the heart, that aberrant conductive pathways constitute peculiar and life threatening patterns, called dysrhythmias, and that **mapping identifies regions along these pathways, called foci, which are then ablated to treat the dysrhythmia**.

Thus, in view of the remarks in Section III and the remarks above, a cardiac mapping electrode, as described by Maguire, is different than a stimulation element as recited in claim 1. The mapping electrode 20 described by Maguire is not a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

Moreover, a person of ordinary skill in the art would readily appreciate the differences between a stimulation electrode as recited in Applicant's claims and known mapping electrodes since mapping electrodes are used before ablation of tissue (as explained in U.S. Patent Nos. 5,964,753 and 6,360,128). Therefore, it logically follows that such mapping electrodes are also used before a lesion is formed since a lesion is formed as a result of ablation. Accordingly, based on what is described by U.S. Patent Nos. 5,964,753 and 6,360,128, it is readily understood that a mapping electrode is not a stimulation electrode since mapping electrodes are used before formation of a lesion, and before use of "a stimulation element configured to emit energy to tissue for stimulating tissue and **evaluating formation of the lesion**..."" as recited in claim 1. Even if a mapping electrode is used after formation of a lesion, the mapping electrode nevertheless operates as a sensor or antenna for receiving and **monitoring** the electrical signals of the heart as opposed to emitting stimulation energy for evaluating formation of a lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

The cited section of Maguire refers to a tip electrode 52, and Maguire further explains that the electrode 52 "is employed **primarily for cardiac mapping**." Maguire (col. 4, lines 47-48) (emphasis added). The cited section of Maguire also explains that the tip electrode 52 will be employed "primarily for sensing of cardiac depolarizations and/or delivery of stimulation pulses, rather than ablation, due to its small size." The Office Action, however, does not explain how sensing cardiac depolarization applies to a stimulation electrode that emits stimulation energy for evaluating the formation of a lesion as recited in Applicant's claims. Further, the cited section of Maguire is silent as to a stimulation element configured to emit energy for stimulating tissue to evaluate formation of a lesion. In fact, Maguire does not even refer to and is not related to evaluating formation of a lesion. The Office Action is otherwise silent in this regard consistent with the deficiencies of Maguire.

Loeb is cited for the purpose of allegedly disclosing a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion. However, the deficiencies of and errors in the interpretation of Loeb are discussed above in Section III, and Loeb does not disclose a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion.

Consequently, neither Maguire nor Loeb discloses "a stimulation element configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion, the stimulation element defining a stimulation element configuration on the distal region of the same relatively short tubular shaft, the stimulation element configuration being different than the ablation element configuration" as recited in claim 1, and the misplaced allegations regarding the cited references cannot support the rejection.

Further, with regard to Maguire and Loeb, to the extent that it is alleged that a mapping electrode inherently is a stimulation electrode configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion by supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion as recited in claim 1, (since the references do not actually disclose these elements), Applicant again notes that the Office Action has not satisfied the inherency requirements and cannot support the rejection since the Office Action relies on allegations that are not supported by, and are inconsistent with, what is actually described by Maguire and Loeb and the known manner in which a cardiac mapping electrode 20 operates. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must

provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

Moreover, to the extent that a scientific theory is relied upon to allege that a mapping electrode is a stimulation electrode as recited in claim 1, Applicant also notes MPEP §2144.02 (The rationale to support a rejection under 35 U.S.C. §103(a), may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided).

In view of these differences and deficiencies, Applicant respectfully submits that Maguire and Loeb, individually and even if somehow properly combined, do not disclose, teach or suggest each element of independent claim 1. Dependent claims 2-6, 9 and 10 incorporate the elements and limitations of independent claim 1 and, therefore, are also believed patentable over the cited references for at least the same reasons. The cited references are also deficient relative to various dependent claims.

Accordingly, Applicant respectfully requests that the rejection of claims 1-6, 9 and 10 under 35 U.S.C. §103(a) be withdrawn.

V. Claims 27-34, 36, 39, 40, 42-44 and 46 Are Patentable Over Maguire in view of Loeb and Dupree

Independent claims 27 and 30 and respective dependent claims 28-29, 31-34, 36, 39, 40, 42-44 and 46 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of Loeb and further in view of U.S. Patent No. 6,542,773 to Dupree *et al.* ("Dupree"). It is conceded that Maguire and Loeb both fail to disclose "a source of stimulation energy" as recited in claims 27 and 30. Office Action (p. 5).

It is then alleged that a source of stimulation energy is "simply a source operatively coupled to the mapping/stimulation electrodes to deliver energy to the mapping/stimulation electrodes" but deficiencies of this allegation and the erroneous interpretation of Loeb are discussed in detail above.

It is further alleged that Loeb discloses that it is known that mapping electrodes not only receive, but also transmit electrical signals. The deficiencies of this allegation are discussed

above in Sections III and IV, and Applicant again notes that claims 27 and 30 refer to a stimulation element that emits stimulation energy to tissue (which is not addressed by these remarks). Various other allegations are also deficient or incorrect as discussed above in Sections III and IV.

Dupree is cited for the limited purpose of allegedly disclosing a stimulator, but does not cure all of the deficiencies of Maguire and Loeb. In view of these differences and deficiencies, Applicant respectfully submits that Maguire, Loeb and Dupree, individually and even if somehow properly combined, do not disclose, teach or suggest each element of independent claims 27 and 30. Dependent claims 28-29, 31-34, 36, 39, 40, 42-44 and 46 incorporate the elements and limitations of independent claims 27 and 30 and, therefore, are also believed patentable over the cited references for at least the same reasons.

Accordingly, Applicant respectfully requests that the rejection of claims 27-34, 36, 39, 40, 42-44 and 46 under 35 U.S.C. §103(a) be withdrawn.

VI. Claims 8 and 48 Are Patentable Over Maguire, Loeb and Haissaguerre

Dependent claims 8 and 48 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of Loeb and Haissaguerre. It is conceded in the Office Action that Maguire fails to disclose at least a portion of a distal region of a relatively short tubular being malleable. Office Action (p. 5). Haissaguerre, however, does not cure the substantial deficiencies of the other cited references as discussed above. Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each element of claims 8 and 48.

Dependent claims 8 and 48 incorporate the elements and limitations of independent claims 1 and 47 and, therefore, are also believed patentable over the cited references for at least the same reasons as discussed above. Accordingly, Applicant respectfully requests that the rejection of claims 8 and 48 under 35 U.S.C. §103(a) be withdrawn.

VII. Claim 35 Is Patentable Over Maguire in view of Loeb, Dupree and Haissaguerre

Dependent claim 35 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maguire in view of Loeb, Dupree and Haissaguerre. Dependent claim 35 incorporates the elements and limitations of independent claim 27 and, therefore, is also believed patentable over the cited references for at least the same reasons as discussed above.

Accordingly, Applicant respectfully requests that the rejection of claim 35 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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